

REMARKS/ARGUMENTS

Claims 75-92 are pending. By way of the present amendment, three (3) claims have been amended and one (1) claim has been cancelled. Applicant respectfully submits that no new matter has been added by way of this amendment. No fees are believed due.

Support for the amended claims can be found throughout the specification and claims as originally filed and in the priority documents for this application. Particular examples of support for amended claim 75 can be found at least at: page 24, lines 16-26; page 26, lines 18-27; page 28, lines 18-27; page 32, lines 1-5; page 34, line 15 – page 37, line 4; page 39, lines 16-23; page 41, line 6 – page 42, line 3; Examples I-IV; and originally filed claims 7-15 and 18-22. Exemplary support for amended claim 75 can be found at least at: page 32, lines 3-5. Claim 91 has been amended to correct dependency.

The present amendments proposed herein are made solely to expedite prosecution of one embodiment of the present invention. Applicant expressly reserves the right to prosecute one or more cancelled claims or any subject matter enabled by the instant specification in one or more continuing applications.

I. FORMALITIES

A. Non-Compliant Amendment

The Office Action dated 4/1/2008 suggested that the amendment document filed 12 July 2004 is considered non-compliant as failing to meet the requirements of 37 C.F.R. § 1.121(1)-(3). Applicant submits that the amendments to the specification as submitted on pages 2-4 of this response are in compliance with 37 C.F.R. § 1.121(1)-(3).

B. Priority

The Office Action dated 4/1/2008 suggested that the instant applications may constitute a continuation-in-part of prior U.S. Application No. 10/407,552. As discussed more below, Applicant respectfully submits that no new matter has been introduced by any amendment and that the instant application has an identical specification as filed in prior application no. 10/407,552, which is a continuation of application no. 10/260,132, filed Sept. 30, 2002, which is a continuation of application no. 09/481,207, filed on Jan. 11, 2000, which is a continuation-in-part of application no. 09/183,422, filed on Oct. 30, 1998, now abandoned, which is a continuation-in-part of application no. 08/680,376, filed on Jul. 15, 1996, now U.S. Pat. No.

5,840,737, which claims priority to U.S. Provisional Application Ser. No. 60/009,608, filed on Jan. 4, 1996.

C. Drawings

The Office Action dated 4/1/2008 objected to Figure 5 because it is handwritten. Applicant hereby submits a replacement drawing sheet for Figure 5 as Exhibit A.

D. Specification

The Office Action dated 4/1/2008 objected to the amendment filed 6/22/2007 as introducing new matter to the disclosure. Without admitting or conceding in any manner that any new matter was introduced in the amendment filed 6/22/2007, Applicant respectfully submits that the objection is moot based on the submission of Preliminary Amendment D on 2/1/2008.

In addition, the Office Action objected to the claims 75-92 because “[t]he preliminary amendment (2/1/2008) lacks status modifiers. See 37 CFR 1.121.” Claims 75-92 were all newly presented in the preliminary amendment filed 2/1/2008, and should have been preceded by the status modifier “(New).” Exhibit B contains the listing of claims for the Preliminary Amendment D filed 2/12008, with each claim preceded by the status modified “(New).” Applicant respectfully submits that the objection is moot in light of the fact that Claims 75-92 from the 2/1/2008 amendment are currently pending and have been the basis of the Office Action dated 4/1/2008. Furthermore, the current listing of amended claims that begin above on page 2 of the instant response includes appropriate status modifiers that indicate status as “Cancelled,” “Previously Presented” or “Currently Amended.”

II. THE REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN.

The Office Action rejected claims 75-82 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully requests that this rejection be withdrawn in light of the current arguments and amendments, made without admitting or conceding in any manner that the rejected claims fail to comply with 35 U.S.C. § 112, first paragraph and solely to expedite the prosecution of the present application.

Prior to determining whether the disclosure satisfies the written description requirement, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for

the various features of the claimed invention. M.P.E.P. § 2163 II.A.2. As such, it is entirely appropriate to look to examples in the specification as support for the claims. *See Capon v. Eshhar*, 418 F.3d 1349, 1360-61 (Fed. Cir. 2005); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1566-68, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991).

Moreover, the pending claims are supported by the specification as filed. According to the Federal Circuit, “[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met.” *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996). Furthermore, “ranges found in applicant’s claims need not correspond exactly to those disclosed in a parent application; the issue is whether one skilled in the art could derive the claimed ranges from the parent’s disclosure.” *Vas-Cath Inc.*, 935 F.2d at 1566, 19 U.S.P.Q.2d 1111. Below is a table that provides the weight percent (“wt-%”) and amounts of disintegrant and buffer for Examples I.A, I.B, I.C, I.D, I.F and I.G.

Example	Disintegrant (wt-%)	Buffer (wt-%)
I.A	66 mg (3.8 wt-%)	975 mg (56 wt-%)
I.B	12 mg (1.8 wt-%)	600 mg (89 wt-%)
I.C	12 mg (1.7 wt-%)	600 mg (88 wt-%)
I.D	12 mg (1.3 wt-%)	850 mg (91 wt-%)
I.F	12 mg (1.9 wt-%)	600 mg (93 wt-%)
I.G	12 mg (1.5 wt-%)	800 mg (97 wt-%)

The Office Action dated 4/1/2008 suggests that there is no support for specific limitations in the proposed claims. Applicant respectfully traverses the rejection and submits that support for the limitations “about 56 to about 97 wt-%” and “about 1 to about 4 wt-%” can be found at least in Examples I.A, I.B, I.C, I.D, I.F and I.G. as demonstrated in the above table. In addition, support for the limitation “about 250 to about 500 mg” in claim 83 can be found at least at Examples I.A, I.B, I.C, I.D, I.F and I.G. As discussed above, additional support for the claimed ranges can be found throughout the specification and examples as filed.

The Office Action also suggests that the limitation “about 1 mEq to about 25 mEq” in Claim 91 lacks support as the disclosure cited by Applicant sets forth 1 mEq in relation to 1 mEq per 2 mg omeprazole. Applicant respectfully submits that support for this limitation can be

found at least at page 93, lines 25-27, describes a tablet comprising “approximately 1 mEq to approximately 25 mEq” sodium bicarbonate.

Based on the present amendments, made solely to expedite the prosecution of the application, Applicant submits that the remainder of the rejection under 35 U.S.C. § 112, first paragraph, is now moot to the extent that it relies on the other limitations identified in the Office Action dated 4/1/2008.

Therefore, the pending claims meet the written description requirement. Applicant respectfully submits that the rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

III. THE REJECTION UNDER 35 U.S.C. § 102/103 SHOULD BE WITHDRAWN.

The Office Action rejected claims 75-86, 88-92 under 102(b) based on Phillips (U.S. Patent No. 6,489,346). The Office Action also rejected claims 75-92 under 35 U.S.C. 103(a) over EP 584,588 (“Nomura”) in view of Carroll and Trudeau (“Carroll”), U.S. Patent No. 5,703,097 to Kim et al. (“Kim”), U.S. Patent No. 6,268,385 to Whittle et al. (“Whittle”).

With respect to the Phillips patent, Applicant submits that no new matter has been introduced by way of the current or any previous amendments. Therefore, U.S. Patent No. 6,489,346 is not available as a 102(b) reference, since the instant application is a continuation of prior application no. 10/407,552, which is a continuation of application no. 10/260,132, filed Sept. 30, 2002, which is a continuation of application no. 09/481,207, filed on Jan. 11, 2000, which issued as U.S. Patent No. 6,489,346. Applicant traverses the rejection and respectfully requests that the rejection under 102(b) be withdrawn in light of the current amendments and remarks.

With respect to the rejection under 103(a) over Nomura in view of Carroll, Kim and Whittle, Applicant respectfully traverses the rejection and requests the rejection be withdrawn in light of the arguments set forth below and the present amendments to the claims.

A. No *prima facie* case of obviousness has been established.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be an apparent reason why a person of ordinary skill would have combined the prior art elements in the manner claimed. Second, there must be a reasonable expectation of success. Third, the references, when combined, must teach or suggest all the claim limitations.

Memorandum from Margaret A. Focarino to U.S.P.T.O. Technology Center Directors dated May

3, 2007 (hereafter “PTO Staff Memo”); M.P.E.P. § 2143. The burden of establishing a *prima facie* case of obviousness lies with the PTO. In determining obviousness, one must focus on the invention as a whole. *Symbol Technologies Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1577-78, 19 U.S.P.Q. 2d 1241 (Fed. Cir. 1991).

As discussed below, no *prima facie* case of obviousness has been established because the Examiner has not demonstrated that the references teach each limitation of the claims. The presently claimed invention provides for a pharmaceutical composition comprising about 10 mg to about 40 mg of non-enteric coated substituted benzimidazole mixed with about 56 to about 97 wt-% of a buffer and excipients consisting essentially of a disintegrant, lubricant and binder. However, none of the references teach or suggest any composition with all of these elements.

Furthermore, the Examiner has not demonstrated (1) an apparent reason why a person of ordinary skill would have combined the prior art elements in the manner claimed; or (2) that one of skill in the art would have had a reasonable expectation of success that the invention currently claimed would work for its intended purpose. Moreover, even if the references are combined, which Applicant believes is improper, the combination of references still fails to render the pending claims obvious because they all fail to teach or suggest each element of the pending claims. Furthermore, objective evidence of non-obviousness supports the patentability of the pending claims.

1. One of skill in the art would not have combined the references.

Applicant respectfully submits that the combination of Carroll and Nomura is improper, because the Office Action fails to identify any suggestion or motivation to combine the references in the manner necessary to arrive at the presently claimed invention. As previously set forth, to establish a *prima facie* case of obviousness when combining multiple references, there must be an “explicit” analysis of both the claimed invention and the prior art to determine “whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l*, 127 S.Ct. 1727, 1733 (2007); PTO Staff Memo, May 3, 2007 (any obviousness rejection must “identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed”). Moreover, there must be “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.*

Applying this rule, Applicant respectfully asserts that the Examiner has failed to identify any reason why a person of ordinary skill in the art at the time of the invention would have combined Nomura, Carroll, Kim and Whittle so as to arrive at the presently claimed invention. In addition, Nomura did not teach or suggest the claimed invention because Nomura, which taught that the buffer to PPI ratio must be less than 20:1 wt-%, used omeprazole as a negative control in Example 1 to show the superiority of its new imidazole PPIs. In fact, Nomura states that omeprazole must be enteric coated:

The omeprazole has been recently launched on market and is now employed as anti-ulcer agent of the proton pump inhibitor type in the form of enteric preparations, such as enteric tablets. It is understood that such proton pump inhibitor type preparations are preferably dissolved in stomach and directly affect walls of the stomach, if the proton pump inhibitor is stable in acidic gastric juice. However, since the known proton pump inhibitor type preparations such as omeprazole and lansoprazole . . . are very rapidly decomposed and inactivated in strong acidic conditions such as pH 1.2 (acidic condition equal to that of the gastric juice of human beings), these are prepared in the form of enteric preparations with enteric coating.

Nomura at 2:12-22.

One of skill in the art would not have combined the teachings in Nomura with the teachings in Carroll because Carroll employed crushed enteric coated omeprazole, which Nomura taught had significantly different properties than the preferred imidazole derivatives of its disclosure. Moreover, Carroll only taught a liquid mixture, which was prepared and then administered via nasogastric tube. Carroll says nothing about solid forms as claimed.

For at least the foregoing reasons, Applicant respectfully submits that no *prima facie* case of obviousness exists because the cited references teach away from both combination with one another as well as the claimed invention.

2. The Office Action fails to show any reasonable expectation of success.

The prior art must provide “a reasonable expectation for success” to establish a basis for a finding of obviousness. *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Under this test, if the prior art provides “no indication of which parameters [are] critical, and [no] direction as to which of many possible choices [is] likely to be successful,” the claimed invention cannot be found to be obvious. *Id.* This principle rests on the recognition that the “genius of invention is often a combination of known elements which in hindsight seems preordained.” *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351 (Fed. Cir. 2001). Carroll is silent as to solid dosage

forms, and it provides no indication that its suspension of crushed pellets could be modified to the claimed invention.

Moreover, it is well known that a given drug substance will have different absorption rates and times of onset depending on the dosage form and excipients, and that these differences are a function of both the formulation and the route of administration. *See e.g.* Ansel et al., Pharmaceutical Dosage Forms and Drug Delivery Systems, Williams & Wilkins, 1995, p. 77. (“An individual drug substance may be formulated into multiple dosage forms which result in different drug absorption rates and times of onset, peak, and duration of action.”). (Exhibit C). This is because, for example, a solid dosage form must first disintegrate and then dissolve before the omeprazole is released, and only after this occurs can the omeprazole be absorbed (assuming that it has not been degraded by stomach acid). Thus, a disclosure of properties in a solution dosage form would not provide a reasonable expectation of success in a solid dosage form as claimed.

Since the Office Action cited no reasonable expectation based on Carroll, Nomura, Kim and Whittle that the combination of references would successfully arrive at the claimed invention, withdrawal of this rejection is respectfully requested. For at least the foregoing reasons, a *prima facie* case of obviousness has not been shown. Accordingly, amended claims 75-92 are not obvious over the cited references. Therefore, Applicant respectfully requests withdrawal of this rejection.

IV. PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 75-92 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 162-196 of copending Application No. 10/407,522. In addition, Claims 75-92 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,780,882. Applicant will submit a terminal disclaimer once allowable subject matter is indicated.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that claims 75-92 are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite

prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

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EXHIBIT A

Replacement Drawing